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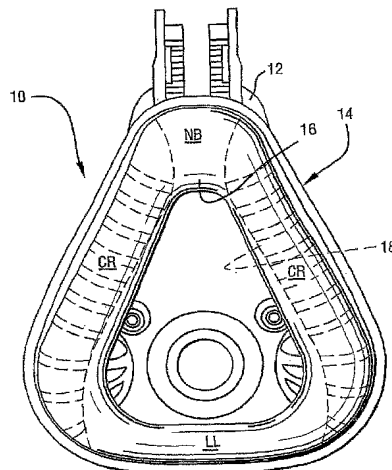
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For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: CUSHION FOR A PATIENT INTERFACE



(57) Abstract: A cushion (14, 214) for a patient interface includes an outer membrane (16, 216) providing a sealed structure adapted to form a seal with the patient's face in use and an underlying membrane (18, 218) generally spaced away from the outer membrane (16, 216). The underlying membrane (18, 218) provides a support structure for the outer membrane (16, 216). The outer membrane (16, 216) and the underlying membrane (18, 218) each have an inner edge which defines an aperture to receive the patient's nose in use. The underlying membrane (18, 218) is segmented along its inner edge.



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## CUSHION FOR A PATIENT INTERFACE

### CROSS-REFERENCE TO THE APPLICATIONS

[0001] This application claims the benefit of Australian Provisional Application No. 2004902979 filed June 3, 2004, incorporated herein by reference in its entirety.

### FIELD OF THE INVENTION

[0002] The invention relates to treatment of sleep disordered breathing. In particular, the invention relates to a cushion for a patient interface used for treatment of sleep disordered breathing.

### BACKGROUND OF THE INVENTION

[0003] The use of nasal Continuous Positive Airway Pressure (nasal CPAP) to treat Sleep Disordered Breathing (SDB), for example Obstructive Sleep Apnea (OSA), was invented by Sullivan (See US Patent 4,944,310). Such treatment is typically accomplished using a source of air at positive pressure (e.g., a blower or flow generator) connected to a patient interface (e.g., a mask) via an air delivery conduit. To maintain a suitable pressure at the entrance to the patient's airways, it is necessary to provide a suitable seal between the patient interface and the patient's face. Early masks were glued to a patient's face every night. Today, however, the patient interface is usually held in position with headgear. Treatment is very successful in reducing SDB. However, gas pressurized in the range of 4-20cmH<sub>2</sub>O can be noisy and uncomfortable. Poorly fitting masks can provide an inadequate seal against leak. After wearing a mask all night, some patients can have pressure sores on their faces, especially in such sensitive regions as the nasal bridge. Thus, mask designers and manufacturers are constantly striving to provide patient interfaces which provide a comfortable seal.

[0004] A variety of masks are available, such as nasal, full-face, and nose and mouth masks.

[0005] ResMed's MIRAGE® mask provided a significant improvement in masks for CPAP treatment. Figs. 1-3 illustrate an embodiment of ResMed's MIRAGE® mask. It is available

in both nasal and full-face versions. In the illustrated embodiment, the mask 2 includes (i) a rigid shell or frame 3 that defines a nose-receiving chamber, and (ii) a face-contacting cushion 4. The cushion 4 plays a role in improving the comfort and seal of the mask. For example, see U.S. Patents 6,112,746; 6,357,441; 6,581,602 and 6,634,358. Other aspects of the mask, such as a forehead support and vent also play a role in the fit, comfort, and noise of a mask.

[0006] As shown in Figs. 4-6, the cushion 4 of the MIRAGE® mask includes a dual membrane structure. As illustrated, the cushion 4 includes a thinner outer membrane 6 that is spaced away from a thicker inner or underlying membrane 8 at their inner edges.

[0007] The present invention is particularly directed towards a cushion with an improved inner or underlying membrane.

#### SUMMARY OF THE INVENTION

[0008] One aspect of the invention relates to a cushion for a respiratory mask having a segmented support structure.

[0009] Another aspect of the invention relates to a cushion for a respiratory mask having a dual membrane structure with an outer membrane and an underlying membrane divided into a series of finger portions.

[0010] Another aspect of the invention relates to a cushion for a patient interface. The cushion includes an outer membrane providing a sealing structure adapted to form a seal with the patient's face in use and an underlying membrane generally spaced away from the outer membrane. The underlying membrane provides a support structure for the outer membrane. The outer membrane and the underlying membrane each have an inner edge which defines an aperture to receive the patient's nose in use. The underlying membrane is segmented along its inner edge.

[0011] Still another aspect of the invention relates to a cushion adapted to be mounted on a frame of a patient interface for use with treatment of sleep disordered breathing. The cushion includes an outer membrane and an underlying membrane. The outer membrane is thinner than the underlying membrane and is generally spaced away from the underlying membrane and in use is adapted to contact a facial region of a patient. The underlying membrane has an

inner edge defining an aperture and is divided along the edge to form a series of finger portions.

[0012] Yet another aspect of the invention relates to a cushion for a patient interface. The cushion includes a membrane and an underlying support structure provided along a side of the cushion to support the membrane. The underlying support structure is segmented.

[0013] Other aspects, features, and advantages of this invention will become apparent from the following detailed description when taken in conjunction with the accompanying drawings, which are a part of this disclosure and which illustrate, by way of example, principles of this invention.

#### BRIEF DESCRIPTION OF THE DRAWINGS

[0014] The accompanying drawings facilitate an understanding of the various embodiments of this invention. In such drawings:

[0015] Figs. 1-3 show various views of a prior art nasal MIRAGE® mask manufactured by ResMed;

[0016] Figs. 4-6 show various views of a prior art cushion for the nasal MIRAGE® mask shown in Figs. 1-3;

[0017] Fig. 7 shows a rear view of a full-face mask according to an embodiment of the invention;

[0018] Fig. 8 shows a bottom detail view of the mask of Fig. 7;

[0019] Fig. 9 shows a top detail view of the mask of Fig. 7;

[0020] Fig. 10 shows a side detail view of the mask of Fig. 7;

[0021] Fig. 11 shows an enlarged perspective view of a cushion according to an alternative embodiment of the invention;

[0022] Fig. 12 shows a top detail view of the cushion of Fig. 11; and

[0023] Figs. 13-14 show rear and side views of a cushion of the mask of Fig. 7, and the cushion opening has not been cut from molding.

#### DETAILED DESCRIPTION OF ILLUSTRATED EMBODIMENTS

[0024] In a dual walled cushion, the outer wall (outer membrane) can define a sealing structure and the inner wall (inner membrane) can define a support structure. A seal can form when a patient's face is lightly pressed against the outer membrane. However, the outer membrane will easily flex upon contact with the patient's face. The inner membrane is generally thicker and more rigid than the outer membrane. When a patient's face presses against the outer membrane, the gap between the two membranes reduces. At a larger contact force, there may be no gap between the two membranes. With a yet higher contact force, the inner membrane will also begin to flex. In response to a contact force from a patient's face to the cushion, the cushion will provide a reaction force from the cushion to the patient's face. The size and direction of the resultant reaction force in a particular region will depend upon the face and cushion properties in that region.

[0025] Fig. 7 illustrates a patient interface in the form of a full-face mask 10 including a cushion 14 in accordance with an embodiment of the invention. The cushion 14 is structured to be attached to a substantially rigid frame 12 associated with an air delivery tube. The cushion 14 may be removably or permanently attached to the frame 12 in any suitable manner.

[0026] As illustrated, the cushion 14 has a thin outer membrane 16 and a thicker underlying membrane 18 generally spaced away from the outer membrane 16. The outer membrane 16 provides a sealing structure to form a seal with the patient's face, and the underlying membrane 18 (also referred to as an underlying support) provides a support structure for the outer membrane 16. Both the outer and underlying membranes 16, 18 have an inner edge which defines an aperture through which a nose passes in use.

[0027] In the illustrated embodiment, the outer membrane 16 forms a seal with a nasal bridge region NB, cheek regions CR, and a lower lip region LL of the patient's face. Also, the cushion 42 has a double-walled construction, i.e., outer membrane 16 and underlying membrane 18, in the cheek regions CR and a single-walled construction, i.e., outer membrane 16, in the nasal bridge and lower lip regions NB, LL. The single wall construction at the top

and bottom of the cushion 14 allows flexibility to accommodate a wide range of patients. However, the cushion 14 may have any other suitable construction, e.g., single walled, triple walled or more walled construction, in any suitable region of the cushion 14.

[0028] As best shown in Figs. 8-10, the underlying membrane 18 is segmented along its inner edge. In the preferred embodiment, the line of segmentation is generally perpendicular to the edge, however in other forms it may not be. The segmentation provides a set of finger portions 17 interconnected by webbing 19.

[0029] In the illustrated embodiment, the underlying membrane 18 is a continuous material with the webbing 19 formed in a different plane than the finger portions 17. However, the webbing 19 may have other suitable configurations. For example, the webbing 19 may be in the form of one or more connecting members that extend between and interconnect at least adjacent portions of adjacent finger portions 17. The one or more connecting members may be positioned between intermediate portions of adjacent finger portions 17 so that tips of the finger portions are exposed. Alternatively, the one or more connecting members may be positioned between end portions of adjacent finger portions 17 so that the connecting members are substantially continuous with tips of the finger portions. Other arrangements are also possible to reinforce and interconnect the finger portions 17.

[0030] Each finger portion 17 is generally independently flexible. That is, a local force on one group of finger portions 17 will not directly transfer to an adjacent group. Thus, flexion of the cushion 14 in one region will not necessarily cause flexion of the cushion 14 in an adjacent region to the same extent as the prior art. This arrangement provides independent suspension of different facial regions in contact with the cushion 14, and allows the cushion 14 to conform more closely to the patient's face.

[0031] Furthermore, in the nasal bridge region NB and lower lip/chin region LL (see Fig. 7), the underlying membrane 18 is progressively or completely shortened. Reducing or eliminating the underlying membrane 18 in these regions of the cushion 14 means the outer membrane 16 can "give" more when a face contacts it. This arrangement can improve comfort in these sensitive regions.

[0032] In one form, the cushion 14 is mechanically equivalent to a series of composite springs placed around a nose receiving aperture of the frame. The composite spring has

mechanical properties derived from the combination of the sealing and support structures, which in one form are two membranes. The properties of the "springs equivalents" in the nasal bridge and lower lip/chin regions NB, LL can be and preferably are different than those in the cheek regions CR (see Fig. 7), in this embodiment.

[0033] Figs. 11 and 12 illustrate a cushion 214 according to another embodiment of the invention. In this embodiment, the cushion 214 includes an outer membrane 216 and underlying membrane 218 segmented into a set of finger portions 217. In contrast the cushion 14, there is no webbing between the finger portions 217 of the cushion 214. Like the previous embodiment, the fingers 217 are progressively shorter in a nasal bridge region NB of the cushion 214 (see Fig. 12). In an embodiment, the depth and/or length of the slot between adjacent finger portions 217 may be selectively adjusted to adjust the flexibility of selected finger portions 217. The depth and/or length of the slot may be adjusted so that the finger portions 217 are more flexible in certain regions of the patient's face.

[0034] In the two above-described embodiments, the cushion 14, 214 is constructed from silicone. However, other materials may be used, such as gel and foam. Figs. 11-12 show a MIRAGE® full face cushion modified in accordance with the invention.

[0035] Other views of the segmented cushion 14 with webbing are shown in Figs. 13 and 14. In these views, the cushion opening has not been cut from molding.

[0036] The cushion 14, 214 described above has several advantages. For example, the cushion 14, 214 is structured to alleviate the pressure of the cushion on the patient's face. Also, the cushion 14, 214 is structured to conform and seal to different patient facial profiles. Further, the cushion 14, 214 is locally compliant.

[0037] Although our invention has been described with reference to particular embodiments, it is to be understood that these embodiments are merely illustrative of the application of the principles of the invention. Numerous modifications may be made therein and other arrangements may be devised without departing from the spirit and scope of the invention. For example, whilst in a preferred embodiment, the cushion includes two membranes, it is also applicable to cushions with one, three or more membranes. Furthermore, the principles of the invention may be applied to a variety of different patient interfaces, such as nasal mask, nose and mouth masks, full-face masks, nasal prongs and nasal cushions. In different

cushions, the role of sealing and support structures can be combined into one physical structure. Fingers may be shaped or adjusted to suit the needs of individual patients.

[0038] Also, the various embodiments described above may be implemented in conjunction with other embodiments, e.g., aspects of one embodiment may be combined with aspects of another embodiment to realize yet other embodiments. In addition, while the invention has particular application to patients who suffer from OSA, it is to be appreciated that patients who suffer from other illnesses (e.g., congestive heart failure, diabetes, morbid obesity, stroke, bariatric surgery, etc.) can derive benefit from the above teachings. Moreover, the above teachings have applicability with patients and non-patients alike in non-medical applications.



**WHAT IS CLAIMED IS:**

1. A cushion (14, 214) for a patient interface comprising:  
an outer membrane (16, 216) providing a sealing structure adapted to form a seal with the patient's face in use; and  
an underlying membrane (18, 218) generally spaced away from the outer membrane (16, 216), the underlying membrane (18, 218) providing a support structure for the outer membrane (16, 216),  
wherein the outer membrane (16, 216) and the underlying membrane (18, 218) each have an inner edge which defines an aperture to receive the patient's nose in use, and the underlying membrane (18, 218) is segmented along its inner edge.
2. A cushion according to claim 1, wherein the segmented underlying membrane (18, 218) is structured to provide local compliance.
3. A cushion according to any one of claims 1-2, wherein the segmented underlying membrane (18, 218) is structured to provide independent suspension of different facial regions in contact with the cushion in use.
4. A cushion according to any one of claims 1-3, wherein the underlying membrane (18, 218) is thicker than the outer membrane (16, 216).
5. A cushion according to any one of claims 1-4, wherein the outer membrane (16, 216) forms a seal with nasal bridge, cheek, and lower lip regions (NB, CR, LL) of the patient's face in use.
6. A cushion according to any one of claims 1-5, wherein the underlying membrane (18, 218) is provided in cheek regions (CR) of the patient's face.
7. A cushion according to any one of claims 1-6, wherein the underlying membrane (18, 218) is segmented to provide a set of finger portions (17, 217).

8. A cushion according to claim 7, wherein at least two of the finger portions (17) are interconnected by webbing (19).

9. A cushion according to any one of claims 7-8, wherein each of the finger portions (17, 217) is independently flexible.

10. A cushion according to any one of claims 1-9, wherein the underlying membrane (18, 218) includes a line of segmentation that extends generally perpendicular to its inner edge.

11. A cushion according to any one of claims 1-10, wherein the underlying membrane (18, 218) is reduced or eliminated in at least one of a nasal bridge region (NB) and a lower lip region (LL) of the patient's face.

12. A cushion (14, 214) adapted to be mounted on a frame of a patient interface for use with treatment of sleep disordered breathing, the cushion (14, 214) comprising:

an outer membrane (16, 216); and

an underlying membrane (18, 218),

the outer membrane (16, 216) being thinner than the underlying membrane (18, 218) and being generally spaced away from the underlying membrane (18, 218) and in use being adapted to contact a facial region of a patient,

the underlying membrane (18, 218) having an inner edge defining an aperture and being divided along the edge to form a series of finger portions (17, 217).

13. A cushion according to claim 12, wherein the finger portions (17) are interconnected by webbing (19).

14. A cushion according to any one of claims 12-13, wherein each of the finger portions (17, 217) is independently flexible.

15. A cushion according to any one of claims 12-14, wherein the underlying membrane (18, 218) includes a line of segmentation that extends generally perpendicular to the edge.

16. A cushion according to any one of claims 12-15, wherein the underlying membrane (18, 218) is reduced or eliminated in at least one of a nasal bridge region (NB) and a lower lip region (LL) of the patient's face.

17. A cushion according to any one of claims 12-16, wherein the underlying membrane (18, 218) provides local compliance.

18. A cushion according to any one of claims 12-17, wherein the underlying membrane (18, 218) provides independent suspension of different facial regions in contact with the cushion in use.

19. A cushion according to any one of claims 12-18, wherein the outer membrane (16, 216) forms a seal with nasal bridge, cheek, and lower lip regions (NB, CR, LL) of the patient's face in use.

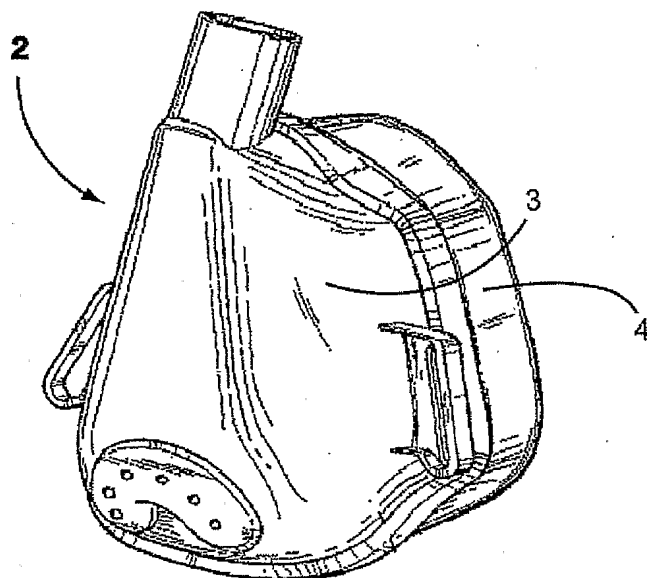
20. A cushion according to any one of claims 12-19, wherein the underlying membrane (18, 218) is provided in cheek regions (CR) of the patient's face.

21. A cushion (14, 214) for a patient interface comprising:  
a membrane (16, 216); and  
an underlying support structure (18, 218) provided along a side of the cushion to support the membrane (16, 216), the underlying support structure being segmented.

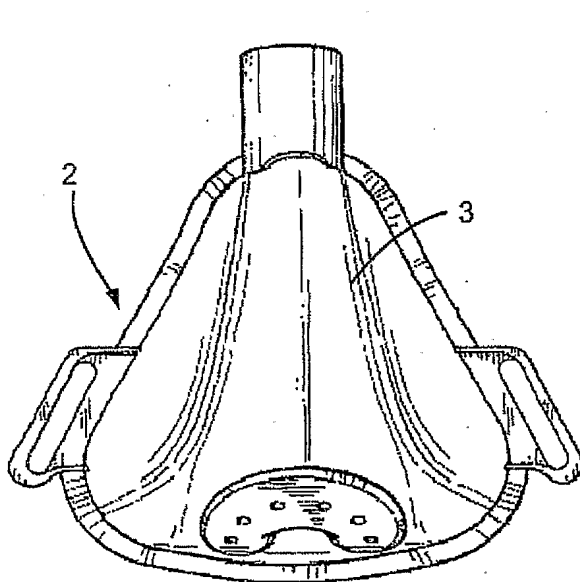
22. A cushion according to claim 21, wherein the underlying support structure (18, 218) is an underlying membrane.

23. A patient interface (10) comprising:  
a frame (12); and  
a cushion (14, 214) according to any one of claims 1-22.

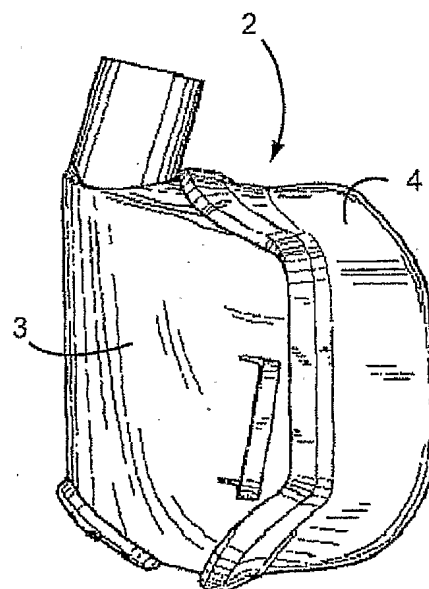
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**Fig. 1**  
(PRIOR ART)



**Fig. 2**  
(PRIOR ART)



**Fig. 3**  
(PRIOR ART)

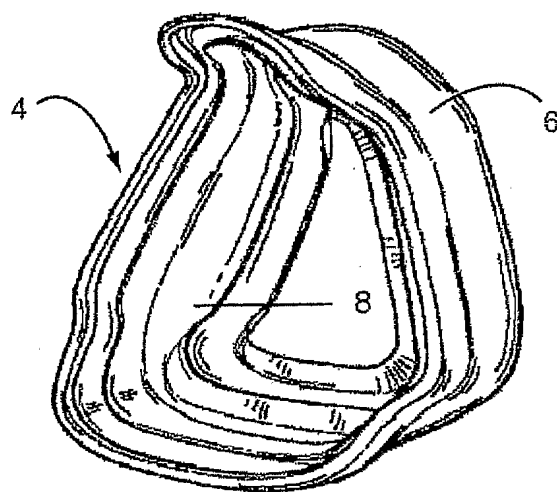


Fig. 4  
(PRIOR ART)

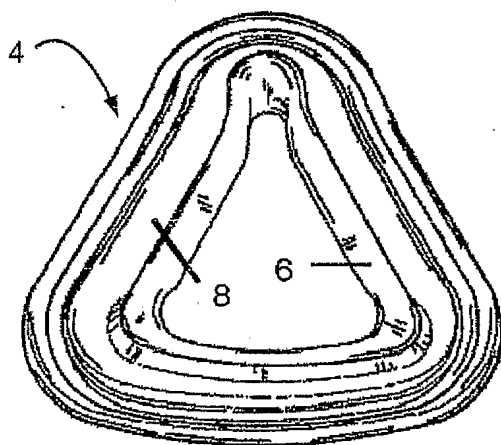


Fig. 5  
(PRIOR ART)

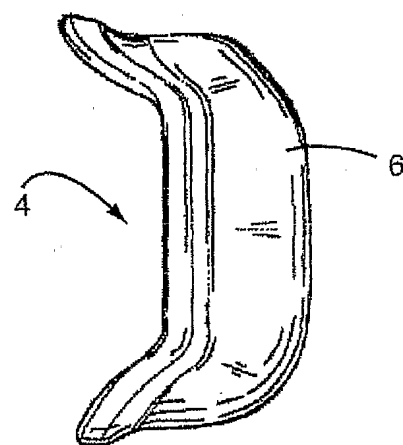


Fig. 6  
(PRIOR ART)

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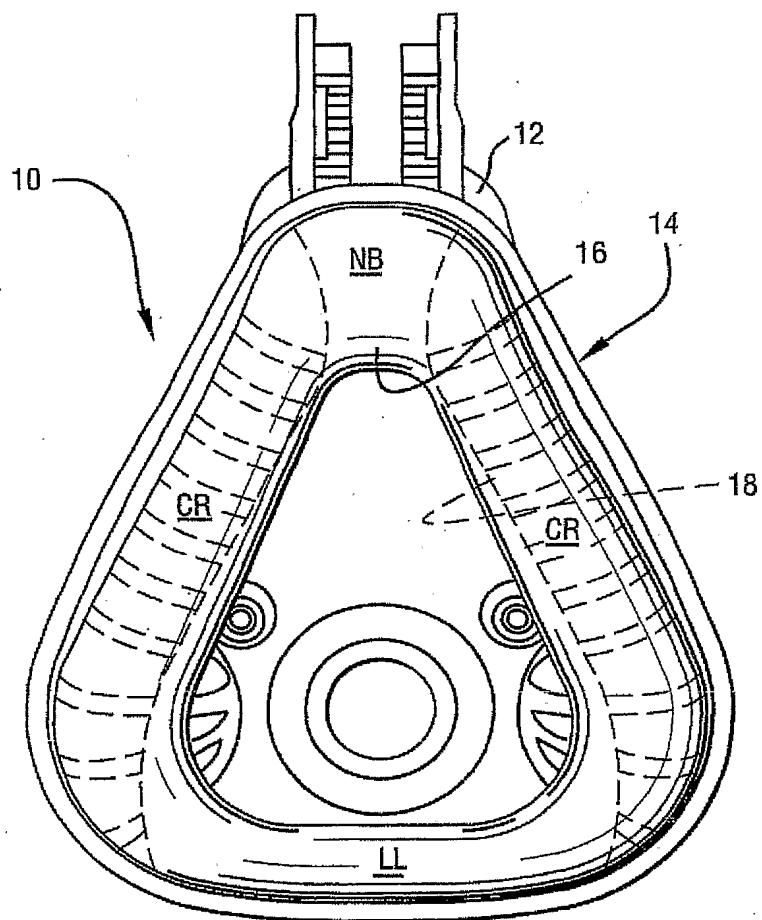


Fig. 7

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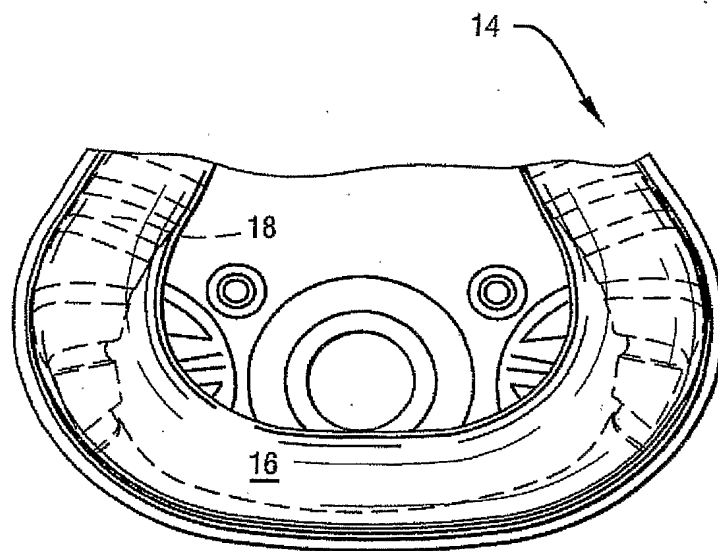


Fig. 8

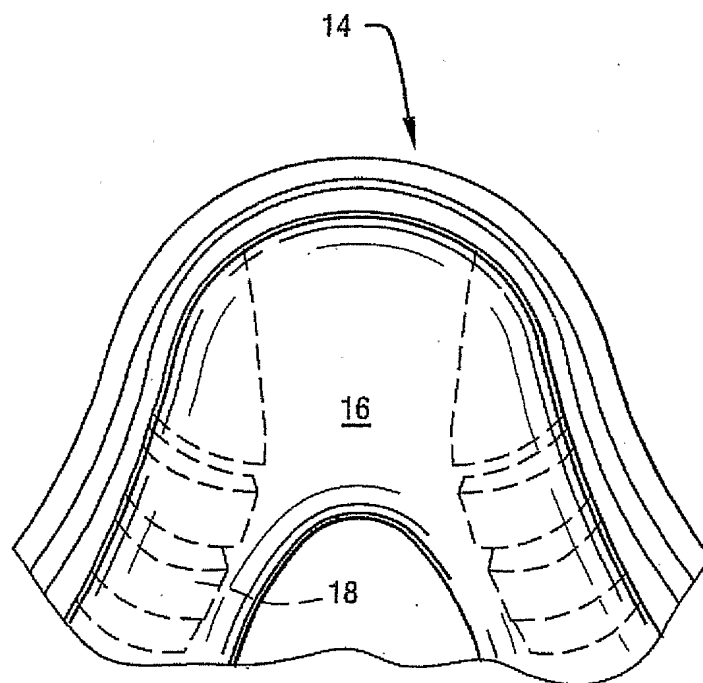


Fig. 9

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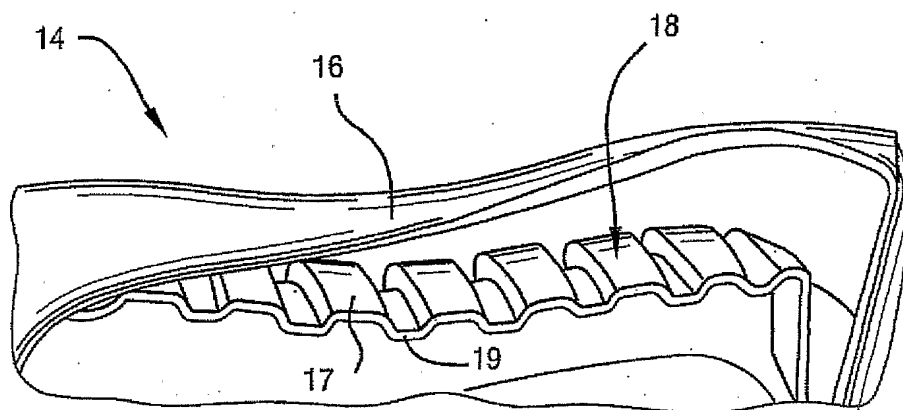


Fig. 10

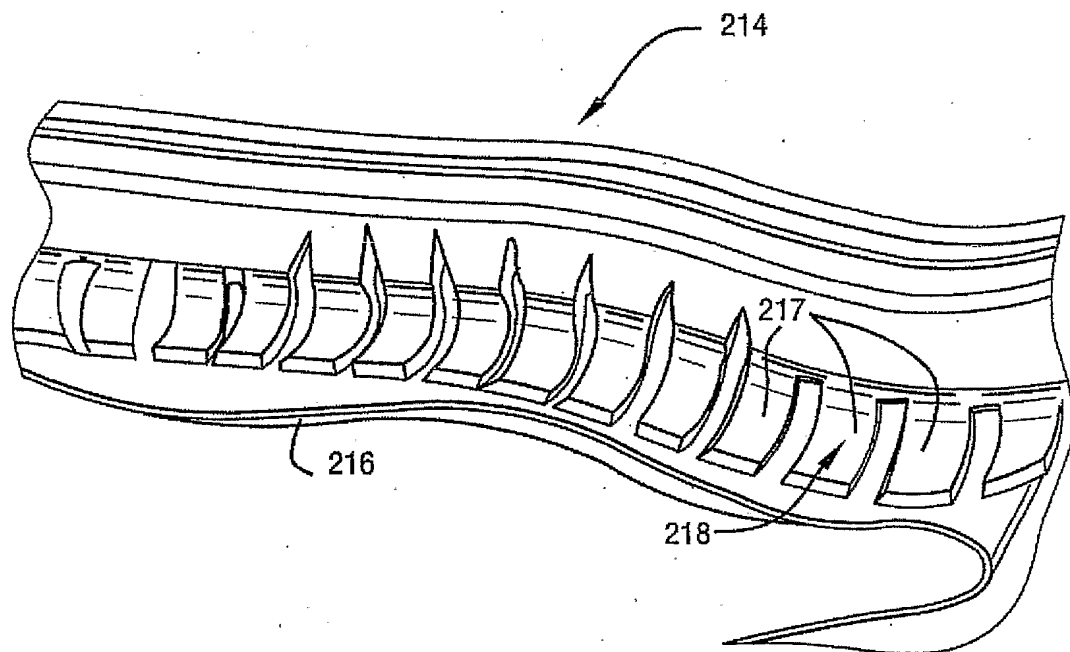


Fig. 11



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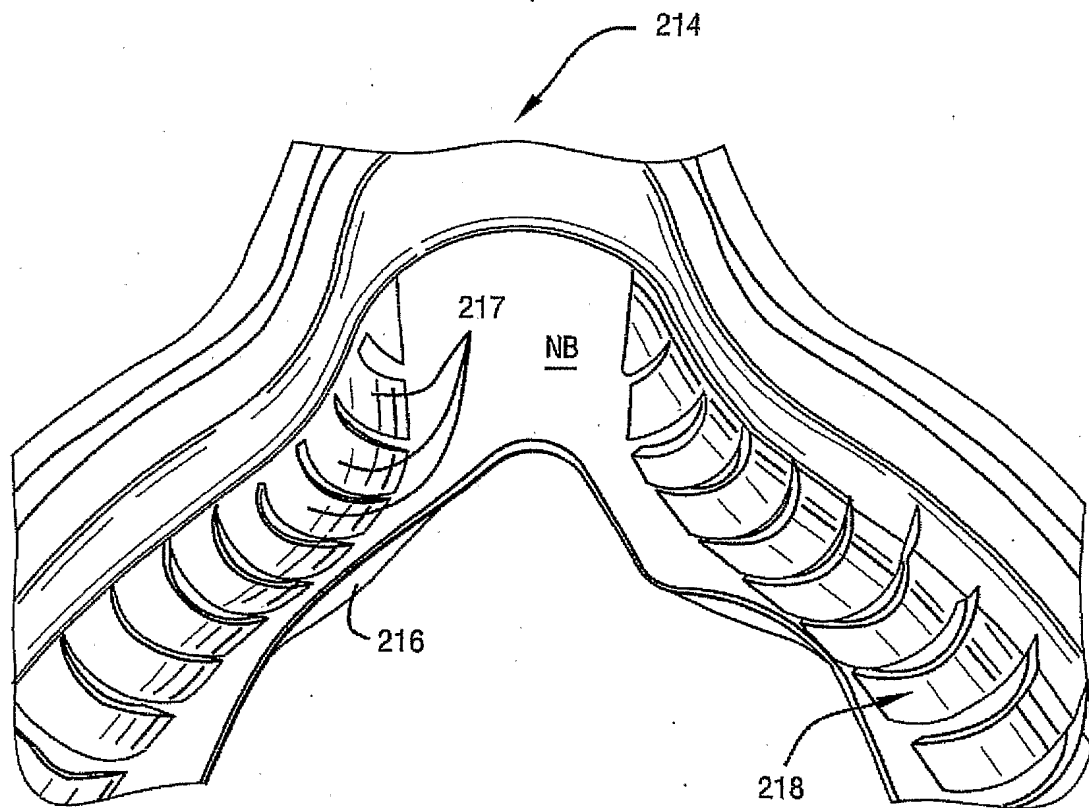


Fig. 12

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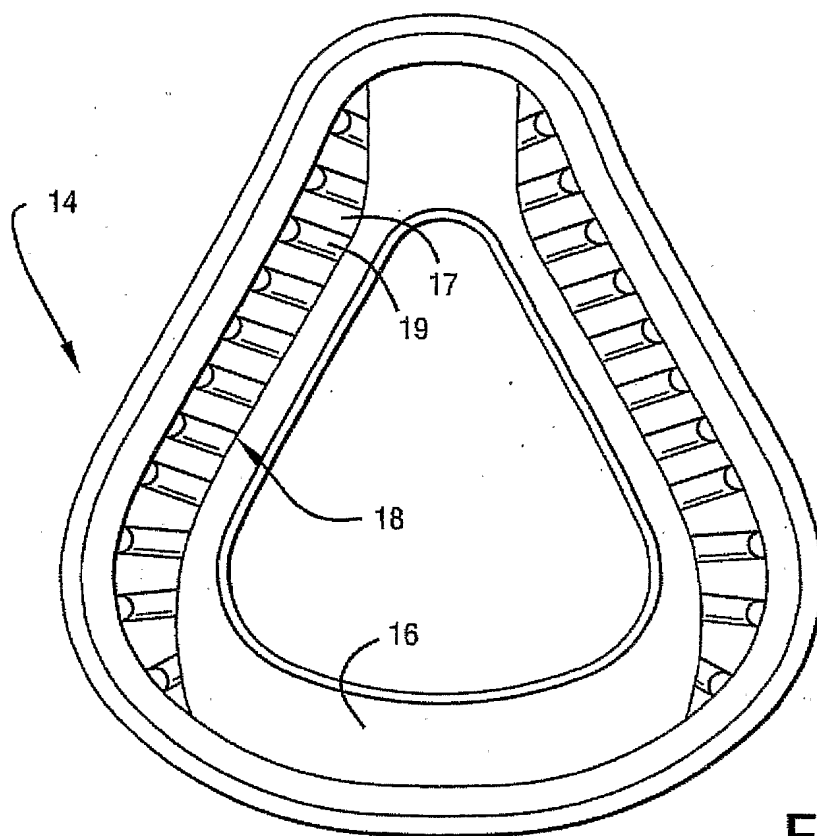


Fig. 13

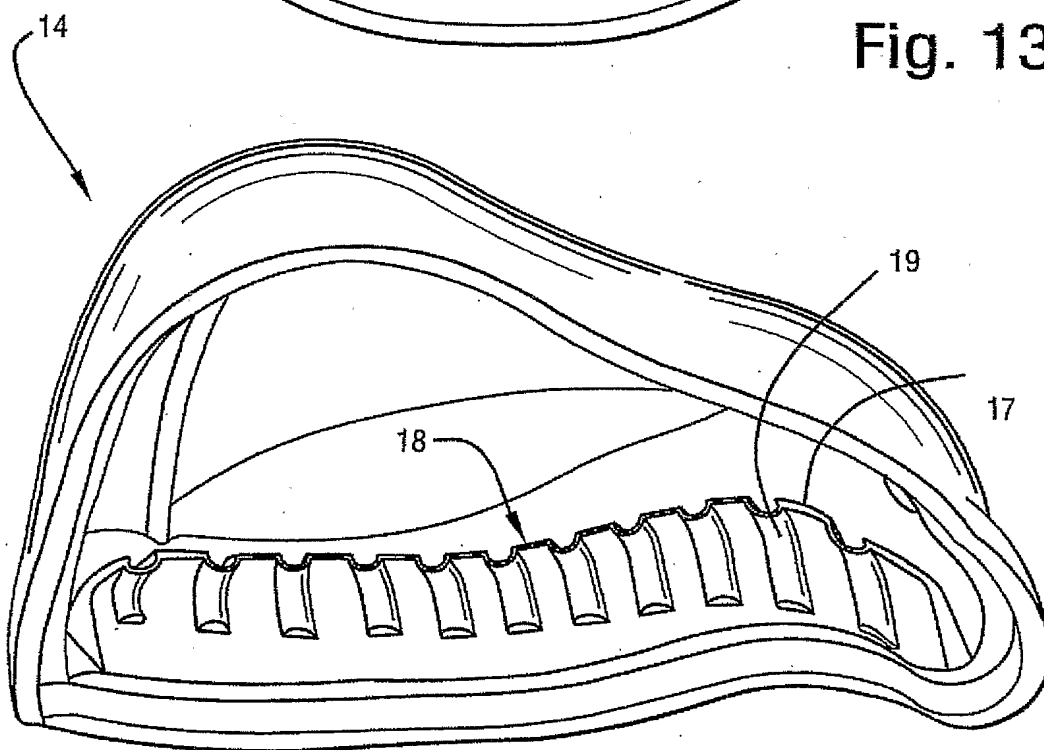


Fig. 14

# INTERNATIONAL SEARCH REPORT

International application No.  
**PCT/AU2005/000803**

<b>A. CLASSIFICATION OF SUBJECT MATTER</b> Int. Cl. <sup>7</sup> : A61M 16/06; A62B 7/00 According to International Patent Classification (IPC) or to both national classification and IPC		
<b>B. FIELDS SEARCHED</b> Minimum documentation searched (classification system followed by classification symbols) Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) DWPI: IPC A61M; A62B & keywords: (interface, mask, cushion, pad, segment, serrated, tooth, teeth, ridged, series, fingers, divides) and similar terms.		
<b>C. DOCUMENTS CONSIDERED TO BE RELEVANT</b>		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2003/0019495 A1 (PALKON ET AL) 30 January 2003 Whole document	1-23
A	US 5655527 A (SCARBERRY ET AL) 12 August 1997 Whole document	1-23
P,A	US 2004/0118406 A1 (LITHGOW ET AL) 24 June 2004 Whole document	1-23
<input type="checkbox"/> Further documents are listed in the continuation of Box C <input checked="" type="checkbox"/> See patent family annex		
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Date of the actual completion of the international search <b>23 June 2005</b>	Date of mailing of the international search report <b>30 JUN 2005</b>	
Name and mailing address of the ISA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaustalia.gov.au Facsimile No. (02) 6285 3929	Authorized officer <b>KAREN VIOLANTE</b> Telephone No : (02) 6283 7933	

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

**PCT/AU2005/000803**

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report				Patent Family Member			
US	2003019495	BR	0201863	CA	2386686	EP	1258266
US	5655527	US	5492116				
US	2004118406	AU	2003257270	AU	2003257271	AU	2003257273
		AU	2003257274	EP	1334742	EP	1539288
		JP	2003175106	US	6812762	US	6823869
		US	2003075180	US	2003080799	US	2003090308
		US	2004112384	US	2004112385	US	2004112387
		US	2005081858	WO	2003/023962	WO	2003/023963
		WO	2004/022144	WO	2004/022145	WO	2004/022146
		WO	2004/022147				
Due to data integration issues this family listing may not include 10 digit Australian applications filed since May 2001.							
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